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IN THE UNITED STATES DISTRICT COURT FOR

THE NORTHERN DISTRICT OF NEW YORK

MELISSA MOORE as Parent and Natural Guardian of the Minor, B.C. Plaintiffs, v. COCHLEAR LIMITED, an Australian Public company; and COCHLEAR AMERICAS, a Delaware Corporation Defendants.	**Case No.** 1:20-cv-753 (MAD/TWD) **COMPLAINT** **JURY TRIAL DEMANDED**

1. Plaintiff MELISSA MOORE as Parent and Natural Guardian of the Minor, B.C. ("Plaintiff") brings this action because a Cochlear Nucleus CI512 cochlear implant medical device ("Subject Cochlear Implant") manufactured, distributed, and sold by Defendants, Cochlear Limited

("CLTD") and Cochlear Americas Corporation ("CAM") failed after it was surgically implanted into Plaintiff's body, requiring further surgery to remove and replace the defective Subject Cochlear Implant.

2. The Cochlear Nucleus CI500 range of cochlear implant medical devices, which includes the Cochlear Nucleus CI512 model that Plaintiff received, were subject to a global recall issued in September 2011, due to an increase in the number of Cochlear Nucleus CI512 implant failures.

3. The United States Food and Drug Administration ("FDA") had previously approved a certain design, materials, construction, manufacturing method, testing, and labeling of Defendants' Cochlear Nucleus CI5l2 cochlear implant medical device pursuant to that agency's premarket approval process ("PMA").

4. Specifically, Defendants' Cochlear Nucleus CI512 cochlear implant medical device was approved as a supplement to PMA P970051, which was originally approved by the FDA on or about June 25, 1998. The PMA supplement for Defendants' Cochlear Nucleus CI512 was approved by the FDA on August 28, 2009.

5. As is more fully set forth herein, Defendants failed to comply with the specifications and requirements of the PMA, federal law and federal regulations. As a result, Plaintiff suffered personal injuries.

6. As a result of Defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations, the Cochlear Nucleus CI500 range of cochlear implant medical devices, including the Cochlear Nucleus CI512, were subject to a global recall issued in September 2011.

7. This recall was predicated upon the Defendants' knowledge that their Cochlear Nucleus CI512 series had experienced an increased failure rate as result of "hermeticity" or sealing compromises in the Cochlear Nucleus CI512 devices, and that these failures were caused by

inexcusable manufacturing defects resulting from Defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations. These same defects caused the failure of Plaintiff's Subject Cochlear Implant as result of "hermeticity" or sealing compromises.

8. As more fully set forth herein, Defendants exposed Plaintiff to the risk of medical device failure, corrective surgery and personal injury, among other things, as a result of Defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations.

9. Plaintiff's claims are premised entirely on Defendants' failure to comply with the PMA, federal law, and federal regulations, subjecting Defendants to liability for Plaintiff's parallel state law claims set forth herein.

10. Plaintiff's parallel state law claims set forth herein will not impose any requirement or standard relating to the safety or effectiveness of the Cochlear Nucleus CI5l2 cochlear implant medical device, or any other matter regulated by the FDA, that is different from, or in addition to, any requirement applicable to the Cochlear Nucleus CI512 cochlear implant medical device under the PMA, federal law, or federal regulations.

11. Plaintiff does not challenge the FDA's approval of the design, manufacturing process, or labeling of a premarket approved medical device in this action. Rather, by pursuing their parallel state law claims set forth herein, Plaintiff seeks to hold Defendants responsible for their injuries and damages proximately caused by the Defendants' failure to comply with the specifications and requirements of the PMA, federal law, and federal regulations with respect to the Subject Cochlear Implant.

12. Plaintiff does not claim herein that the Subject Cochlear Implant should have been designed, manufactured, tested, marketed, or labeled in a manner different from that approved by the FDA.

13. Rather, as more fully set forth herein, Plaintiff claims that, with respect to the Subject Cochlear Implant, Defendants' failure to comply with the specifications and requirements of the PMA, federal law, and federal regulations proximately caused them to suffer injuries and damages of a personal and pecuniary nature.

14. As more fully set forth herein, the Subject Cochlear Implant that Plaintiff received was not manufactured according to the specifications and requirements of the PMA, federal law, and

PARTIES

15. Plaintiff is a United States citizen and resident of the State of New York, domiciled in Stottville, Columbia County, New York.

16. Defendant Cochlear Limited ("CLTD") is an Australian public company with its principal place of business in New South Wales, Australia.

17. CLTD holds itself out as "The leading global expert in implantable hearing solutions."

18. Defendant Cochlear Americas Corporation ("CAM") is a Delaware corporation with its principal place of business in Centennial, Colorado

19. CAM is a wholly owned subsidiary of CLTD.

20. CLTD established and maintains CAM as its wholly owned subsidiary for the purpose of conducting business on behalf of and for the benefit of CLTD in the United States, including in the forum state of New York.

21. CLTD represents in its Annual Report of 2016 that it maintains its “regional headquarters in Denver, US.”

22. CLTD purposefully directs and sells it cochlear implants into the State of New York. On its website, CLTD lists 30 separate cochlear implant clinics in the State of New York to obtain its implants. Specific to this case, CLTD directs patients, including the minor plaintiff, to the Albany Medical Center, which is where the minor Plaintiff underwent surgeries both to implant

and remove the Subject Cochlear Implant.

23. CLTD caused the Subject Cochlear Implant to be shipped to and tested at its facility in Australia for post-explant failure analysis.

24. CLTD established and maintains CAM to create, control, and employ the distribution system that bring CLTD's products into the United States, including the Subject Cochlear Implant into the forum state of New York.

25. At all times relevant, CLTD, through its directors, officers, employees, and managing agents, had actual knowledge that the products that it manufactured, including the Subject Cochlear Implant, were being marketed and sold in the forum state of New York.

26. At all times relevant herein, CAM's actions in the United States, including in the forum state of New York, on behalf of and for the exclusive benefit of CLTD, include sales, marketing, distribution, service, finance, regulatory and administration of CLTD's products, including the Subject Cochlear Implant.

27. At all times relevant, the products that CLTD manufactures, including the Subject Cochlear Implant, have been sold and distributed exclusively in the United States and the New York forum through CAM.

28. At all times relevant, CAM's sales revenue for CLTD's products in the United States, including New York, have been included in CLTD's revenue figures reported in its Annual Reports.

29. At all times relevant, CAM's employees have been included in CLTD's reporting of its total number of employees in its Annual Reports.

30. CLTD purposefully availed itself on a frequent and regular basis to the laws and protections of the United States of America by applying to the United States Patent and Trademark Office on at least 26 occasions over the past 20 years for trademark and service mark protection. CLTD has

been granted trademark and service mark protection on at least 26 occasions in the United States, each time purposefully availing itself to the benefits and protections of United States law for the purpose of selling cochlear implants in the United States, as follows:

31. On July 20, 2000, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "NRT" relating to "[c]omputer software…to control, operate and modify the operation of implantable electronic medical devices" for the Subject Cochlear Implant. On October 19, 2004, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 2896018.

32. On March 30, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for the image and word Cochlear® relating to "battery chargers and battery rechargers," for the Subject Cochlear Implant. On September 6, 2008, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3502095.

33. On March 30, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "COCHLEAR" relating to "batteries and battery rechargers." On September 16, 2008, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark and service mark with Registration Number 3502096.

34. On March 30, 2004, Defendant CLTD filed with the United States Patent and Trademark

Office an application for trademark protection for relating to "batteries, rechargeable electric batteries" for the Subject Cochlear Implant. On May 8, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3240207.

35. On March 30, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for relating to "implantable prosthetic hearing devices and associated accessories and monitoring equipment" for the Subject Cochlear Implant. On September 19, 2006, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3145952.

36. On March 30, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "COCHLEAR" relating to "[i]nterface devices for programming prosthetic hearing implants" for the Subject Cochlear Implant. On January 23, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3200044.

37. On March 30, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for the image and word Cochlear® relating to

"implantable prosthetic hearing devices and associated accessories" for the Subject Cochlear Implant. On March 30, 2010, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3767745.

38. On April 14, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "ADVANCE OFF-STYLET" relating to "surgical instruments for use in the implantation of prosthetic hearing devices" for the Subject Cochlear Implant. On October 9, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3307758.

39. On June 29, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "CONTOUR" relating to "surgical instruments…for use in the implantation of prosthetic hearing devices" for the Subject Cochlear Implant. On September 11, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3291318.

40. On July 6, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "NUCLEUS" relating to "[m]edical electronic apparatus and implants, namely, hearing prosthesis" for the Subject Cochlear Implant. On January 23, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3047821

41. On July 19, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "CONTOUR ADVANCE" relating to "surgical instruments…for use in the implantation of prosthetic hearing devices" for the Subject Cochlear Implant. On July 31, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3272721.

42. On August 12, 2004, Defendant CLTD filed with the United States Patent and Trademark

Office an application for trademark protection for "CUSTOM SOUND" relating to "software for fitting, diagnosing and programming prosthetic hearing devices and implants" for the Subject Cochlear Implant. On September 11, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3292387.

43. On August 12, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "FREEDOM" relating to "implantable prosthetic hearing devices and associated accessories" for the Subject Cochlear Implant. On February 6, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3206522.

44. On August 12, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "FREEDOM" relating to "implantable prosthetic hearing devices and associated accessories" for the Subject Cochlear Implant. On February 6, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3206522.

45. On August 26, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "BEAM" relating to "[m]edical electronic apparatus, namely, implantable prosthetic hearing devices and associated accessories" for the Subject Cochlear Implant. On February 12, 2008, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3382348.

46. On September 7, 2004, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "SMARTSOUND" relating to "[m]edical electronic apparatus, namely, implantable prosthetic hearing devices and associated accessories" for the Subject Cochlear Implant. On December 4, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number

3349004.

47. On May 24, 2005, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "AUTONRT" relating to "computer software…to control, operate and modify the operation of implantable electronic medical devices" for the Subject Cochlear Implant. On April 24, 2007, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3234050.

48. On March 3, 2006, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for the image and word Cochlear® "COCHLEAR" relating to "surgical devices relating to the implantation of prosthetic hearing devices" for the Subject Cochlear Implant. On March 4, 2008, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3390528.

49. On June 17, 2008, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "HEAR NOW AND ALWAYS" relating to "implantable medical electronic apparatus, namely implantable prosthetic hearing devices and associated accessories," for the the Subject Cochlear Implant. On May 18, 2010, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3790772. "HEAR NOW AND ALWAYS," is the phrase that COCHLEAR LIMITED used and still uses to advertise the quality of its cochlear implants, including the Subject Cochlear Implant, and is the representation that the minor's parents relied upon when choosing the Subject Cochlear Implant from Defendant, CLTD, instead of the product

from CLTD's competitor.

50. On June 17, 2008, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection for "HEAR NOW AND ALWAYS" relating to the medical software for fitting, diagnosing and programming "prosthetic hearing devices and implants" such as the Subject Cochlear Implant. On March 1, 2011, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark with Registration Number 3925986. "HEAR NOW AND ALWAYS," is the phrase that COCHLEAR LIMITED used and still uses to advertise the quality of its cochlear implants, including the Subject Cochlear Implant, and is the representation that the minor's parents relied upon when choosing the Subject Cochlear Implant from Defendant, CLTD, instead of the product from CLTD's competitor.

51. On June 17, 2008, Defendant CLTD filed with the United States Patent and Trademark Office an application for service mark protection for "HEAR NOW AND ALWAYS" relating to audiologist services, therapy services and surgery services for "the implantation of prosthetic hearing devices and components thereof, such as the Subject Cochlear Implant. On November 11, 2008, the United States Patent and Trademark Office granted the request of CLTD and registered the service mark with Registration Number 3822461. "HEAR NOW AND ALWAYS," is the phrase that COCHLEAR LIMITED used and still uses to advertise the quality of its cochlear implants, including the Subject Cochlear Implant, and is the representation that the minor's parents relied upon when choosing the Subject Cochlear Implant from Defendant, CLTD, instead of the product from CLTD's competitor.

52. On February 11, 2011, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection and service mark protection for "CODACS" relating to "prosthetic implantable hearing devices" such as the Subject Cochlear Implant. On January 6, 2015, the United States Patent and Trademark Office granted the request of CLTD and

registered the trademark and service mark with Registration Number 4665424.

53. On June 30, 2011, Defendant CLTD filed with the United States Patent and Trademark Office an application for service mark protection for "MYCOCHLEAR" relating to the design and development of computer hardware and software, provision of online non-downloadable software, and the creation of an on-line community for users of its Cochlear Implants, including the Subject Cochlear Implant. On September 11, 2012, the United States Patent and Trademark Office granted the request of CLTD and registered the service mark with Registration Number 4204119.

54. On June 30, 2011, Defendant CLTD filed with the United States Patent and Trademark Office an application for trademark protection and service mark protection for "COCHLEAR" relating to "non-cochlear implant prosthetic implantable hearing devices." On October 7, 2014, the United States Patent and Trademark Office granted the request of CLTD and registered the trademark and service mark with Registration Number 4615507.

55. On November 20, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for service mark protection for "COCHLEAR" relating to CLTD's business management services, billing services, marketing services and advertising services for prosthetic hearing devices, including the Subject Cochlear Implant. On February 26, 2019, the United States Patent and Trademark Office granted the request of CLTD and registered the service mark with Registration Number 1388179.

56. On November 20, 2017, Defendant COCHLEAR filed with the United States Patent and Trademark Office an application for service mark protection for "NUCLEUS" relating to CLTD's business management services, billing services, marketing services, advertising services, and software services for the programming, testing, controlling and managing of prosthetic hearing devices, including the Subject Cochlear Implant. In fact, the Subject Cochlear Implant is referred

to by Defendant CLTD as the "Nucleus." This application was based on an earlier application and approval for the same word. The United States Patent and Trademark Office granted the request of CLTD and registered the service mark with Registration Number 1400736.

57. CLTD purposefully availed itself on a frequent and regular basis to the laws and protections of the United States of America by applying to the United States Patent and Trademark Office over 100 times over the past 13 years for patent protection. CLTD has been granted patent protection for over 100 patents in the United States, each time purposefully availing itself to the benefits and protections of United States law for the purpose of selling cochlear implants in the United States, as follows:

58. On August 16, 2007 Defendant CLTD filed an application for patent protection for "Recognition of Implantable Medical Device" for its cochlear implants. On June 9, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number RE48,038.

59. On November 10, 2008 Defendant CLTD filed an application for patent protection for "Spanning Connector For Implantable Hearing Instrument" for its cochlear implants. On May 5, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,645,502.

60. On March 10, 2009 Defendant CLTD filed an application for patent protection for "Feedthrough Arrangement For Medical Device" for its cochlear implants. On March 3, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,576,275.

61. On November 1, 2011, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Sound Processing With Increased Noise Suppression" for its cochlear implants. On September 17, 2019, the United States Patent and

Trademark Office granted the request and issued CLTD Patent Number 10,418,047.

62. On February 14, 2012, Defendant CLTD filed an application for patent protection for "Customization Of Bone Conduction Hearing Devices" for its bone-anchored hearing devices. On January 7, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,531,208.

63. On May 31, 2012, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Convertibility Of A Bone Conduction Device" for its bone-anchored hearing devices. On September 17, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,419,861.

64. On September 28, 2012, Defendant CLTD it filed with the United States Patent and Trademark Office an application for patent protection for "Adjustable Fixation Device Having Reduced Infection" for its cochlear implants. On July 23, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,362,417.

65. On June 24, 2013 Defendant CLTD filed an application for patent protection for "Observer-Based Cancellation System for Implantable Hearing Instruments" for its cochlear implants. On January 21, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,542,350.

66. On October 11, 2013, Defendant CLTD it filed with the United States Patent and Trademark Office an application for patent protection for "Devices For Enhancing Transmissions Of Stimuli In Auditory Prostheses" for its bone-anchored hearing devices. On October 22, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,455,336.

67. On November 18, 2014, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Own Voice Body Conducted Noise Management"

for its cochlear implants. On April 9, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,257,619.

68. On April 24, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Multi-Electrode Channel Configurations" for its cochlear implants. On May 28, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,300,290.

69. On May 19, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Removable Attachment Of A Passive Transcutaneous Bone Conduction Device With Limited Skin Deformation" for its cochlear implants. On April 2, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,251,003.

70. On August 21, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Suspended Components In Auditory Prostheses" for its bone-anchored hearing devices. On November 5, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,469,963.

71. On August 27, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Bone Fixture For Medical Prosthesis" for its cochlear implants. On August 13, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,376,269.

72. On September 11, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Configuration Of Hearing Prosthesis Sound Processor Based On Visual Interaction With External Device" for its cochlear implants. On November 19, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,484,801.

73. On September 24,2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Feedback Path Evaluation Based On An Adaptive System" for its cochlear implants. On May 28, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,306,377.

74. On September 25, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Implant Magnet System" for its cochlear implants. On March 19, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,232,171.

75. On September 25, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Relay Interface For Connecting An Implanted Medical Device To An External Electronics Device" for its cochlear implants. On November 26, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,485,974.

76. On September 30, 2015, Defendant COCHLEAR filed with the United States Patent and Trademark Office an application for patent protection for "Method And Device For Intracochlea Impedance Measurement" for its cochlear implants. On May 7, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,278,610.

77. On October 19, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Implantable Auditory Prosthesis With Floating Mass Transducer" for its cochlear implants. On July 2, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,341,789.

78. On October 19, 2015, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Smoothing Power Consumption Of An Active Medical Device" for its cochlear implants. On August 20, 2019, the United States Patent and

Trademark Office granted the request and issued CLTD Patent Number 10,390,153.

79. On December 8, 2015, Defendant CLTD filed an application for patent protection for "Impulse Noise Management" for its cochlear implants. On January 7, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,525,265.

80. On January 26, 2016 Defendant CLTD filed an application for patent protection for "DACS Actuator" for its cochlear implants. On March 17, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,595,141.

81. On January 28, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Advanced Management Of An Implantable Sound Management System" for its cochlear implants. On May 7, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,284,968.

82. On March 8, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Integrated Implantable Hearing Device, Microphone And Power Unit" for its cochlear implants. On October 2, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,449,376.

83. On March 10, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Auditory Signal Processing" for its cochlear implants. On July 2, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,335,591.

84. On March 14, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Prosthesis Adapter" for its cochlear implants. On September 24, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,425,750.

85. On March 18, 2016, Defendant CLTD filed with the United States Patent and Trademark

Office an application for patent protection for "Input selection for an auditory prosthesis" for its cochlear implants. On September 10, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,406,359.

86. On March 26, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Dual Power Supply" for its cochlear implants. On September 24, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,425,751.

87. On March 27, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Tinnitus Masking In Hearing Prostheses" for its cochlear implants. On March 5, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,225,671.

88. On May 18, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Wireless Communication In An Implantable Medical Device System" for its cochlear implants. On February 19, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,207,117.

89. On May 18, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Micro-Charge Stimulation" for its cochlear implants. On July 9, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,342,975.

90. On May 18, 2016 Defendant CLTD filed an application for patent protection for "Execution And Initialisation Of Processes For A Device" for its cochlear implants. On April 7, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,616,695.

91. On May 18, 2016 Defendant CLTD filed an application for patent protection for "Implant

Infection Control" for its cochlear implants. On January 21, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,537,743.

92. On May 18, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Bone conduction devices utilizing multiple actuators" for its bone-anchored hearing devices. On September 10, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,412,510.

93. On May 19, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Audio Logging For Protected Privacy" for its cochlear implants. On March 19, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,237,664.

94. On May 24, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Neutralizing The Effect Of A Medical Device Location" for its cochlear implants. On August 27, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,397,710.

95. On May 25, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "External Component With Inductance And Mechanical Vibratory Functionality" for its cochlear implants. On June 11, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,321,247.

96. On May 26, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Device Monitoring For Program Switching" for its cochlear implants. On March 26, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,244,332.

97. On May 26, 2016 Defendant CLTD filed an application for patent protection for "Electrode

Selection" for its cochlear implants. On January 21, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,537,739.

98. On June 9, 2016 Defendant CLTD filed an application for patent protection for "Advanced Scene Classification For Prosthesis" for its cochlear implants. On April 21, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,631,101.

99. On June 21, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Automated Inner Ear Diagnoses" for its cochlear implants. On May 21, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,292,644.

100. On June 30, 2016 Defendant CLTD filed an application for patent protection for "Systems And Methods For Alerting Auditory Prosthesis Recipient" for its cochlear implants. On January 28, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,543,371.

101. On July 7, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Integrity Evaluation System In An Implantable Hearing Prosthesis" for its cochlear implants. On March 5, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,220,201.

102. On July 11, 2016 Defendant CLTD filed an application for patent protection for "Individualized Rehabilitation Training of A Hearing Prosthesis Recipient" for its cochlear implants. On February 5, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,198,964.

103. On July 12, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Hearing Prosthesis Programming" for its cochlear

implants. On July 23, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,357,656.

104. On July 14, 2016 Defendant CLTD filed an application for patent protection for "Cartridge For An Electrode Array Insertion Device" for its cochlear implants. On January 28, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,543,125.

105. On July 18, 2016 Defendant CLTD filed an application for patent protection for "Traducer Management" for its cochlear implants. On March 24, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,602,284.

106. On July 18, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Integrity Management Of An Implantable Device" for its cochlear implants. On November 12, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,477,332.

107. On July 26, 2016, Defendant CLTD filed an application for patent protection for "Implantable Medical Device Charging" for its cochlear implants. On December 17, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,511,189.

108. On August 2, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Implantable Medical Device Arrangements" for its cochlear implants. On March 26, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,238,871.

109. On August 24, 2016, Defendant CLTD filed an application for patent protection for "Monitoring Stimulating Assembly Insertion" for its cochlear implants. On December 10, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent

Number 10,500,392.

110. On August 24, 2016 Defendant CLTD filed an application for patent protection for "Hearing Aid Adapter" for its cochlear implants. On February 4, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,555,095.

111. On September 22, 2016 Defendant CLTD filed an application for patent protection for "Coupling Apparatuses For Transcutaneous Bone Conduction Devices" for its cochlear implants. On January 21, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,542,351.

112. On September 28, 2016 Defendant CLTD filed an application for patent protection for "Perception change-based adjustments in hearing prostheses" for its cochlear implants. On February 5, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,194,814.

113. On October 24, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Fitting Of Hearing Devices" for its bone-anchored hearing devices. On September 10, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,412,515.

114. On November 23, 2016 Defendant CLTD filed an application for patent protection for "Magnet Placement and Antenna Placement of An Implant" for its cochlear implants. On June 2, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,674,287.

115. On November 28, 2016 Defendant CLTD filed an application for patent protection for "Removable Auditory Prosthesis Interface" for its cochlear implants. On November 12, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number D866,767.

116. On December 15, 2016, Defendant CLTD filed an application for patent protection for "Isolated Actuator For Bone Conduction Device" for its cochlear implants. On January 29, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,194,254.

117. On December 30, 2016, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Bone Bed Drilling Template" for its cochlear implants. On July 23, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,357,329.

118. On January 13, 2017 Defendant CLTD filed an application for patent protection for "Fixation System For An Implantable Medical Device" for its cochlear implants. On April 7, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,610,691.

119. On January 21, 2017, Defendant CLTD filed an application for patent protection for "Impulse-Aware Sound Processing" for its cochlear implants. On November 26, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,492,007.

120. On January 23, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Electromechanical Transducer With Mechanical Advantage" for its bone-anchored hearing devices. On October 15, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,448,136.

121. On January 24, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Passive Vibration Cancellation System For Microphone Assembly" for its cochlear implants. On May 28, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,306,385.

122. On January 26, 2017 Defendant CLTD filed an application for patent protection for "Feedthrough Arrangement For Medical Device" for its cochlear implants. On February 11, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,556,115.

123. On February 7, 2017 Defendant CLTD filed an application for patent protection for "Sound Processing Based On A Confidence Measure" for its cochlear implants. On April 2, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,249,324.

124. On February 9, 2017 Defendant CLTD filed an application for patent protection for "Execution And Initialisation Of Processes For A Device" for its cochlear implants. On April 14, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,616,695.

125. On February 9, 2017 Defendant CLTD filed an application for patent protection for "Rechargeable Battery Voltage Adaption" for its cochlear implants. On April 14, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,620,243.

126. On March 9, 2017, Defendant CLTD filed an application for patent protection for "Multi-Loop Implant Charger" for its cochlear implants. On January 7, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,530,177.

127. On March 20, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Prosthesis Adapter" for its cochlear implants. On June 25, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,334,374.

128. On May 22, 2017, Defendant CLTD filed with the United States Patent and Trademark

Office an application for patent protection for "Configuration Of Hearing Prosthesis Sound Processor Based On Control Signal Characterization Of Audio" for its cochlear implants. On February 26, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,219,081.

129. On March 22, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Implant Heat Protection" for its cochlear implants. On April 9, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,265,533.

130. On April 3, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Wearable Band For Facilitating Hearing" for its cochlear implants. On May 7, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,284,973.

131. On April 3, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Epidermal Down-Growth Barrier" for its cochlear implants. On February 19, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,206,820.

132. On April 7, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Electrocochleography Testing In Hearing Prostheses" for its cochlear implants. On September 17, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,413,728.

133. On April 24, 2017, Defendant CLTD filed an application for patent protection for "Implantable Auditory Stimulation System And Method With Offset Implanted Microphones" for its cochlear implants. On December 24, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,516,953.

134. On April 28, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Body noise reduction in auditory prostheses" for its cochlear implants. On November 5, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,463,476.

135. On April 28, 2017 Defendant CLTD filed an application for patent protection for "Implanted Magnet Management In The Face Of External Magnetic Fields" for its cochlear implants. On March 3, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,576,276.

136. On May 12, 2017 Defendant CLTD filed an application for patent protection for "Power and Data Transfer In Hearing Prostheses" for its cochlear implants. On April 28, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,632,317.

137. On May 18, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Implant Charging Protection" for its cochlear implants. On July 23, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,357,659.

138. On May 22, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Implantable Auditory Prosthesis Usage Restriction" for its cochlear implants. On July 23, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,357,658.

139. On July 5, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Automatic Determination Of The Threshold Of An Evoked Neural Response" for its cochlear implants. On October 12, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,449,357.

140. On July 6, 2017 Defendant CLTD filed an application for patent protection for "Bracket For A Sound Processor And A Coil" for its cochlear implants. On May 28, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number D849,954.

141. On July 20, 2017, Defendant CLTD filed an application for patent protection for "Cochlear Implant Electrode Assembly Insertion Tool" for its cochlear implants. On January 21, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,537,708.

142. On August 7, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Waterproof Molded Membrane For Microphone" for its cochlear implants. On February 19, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,212,524.

143. On August 16, 2017, Defendant CLTD filed an application for patent protection for "Charging-Induced Implant Operation" for its cochlear implants. On January 7, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,525,271.

144. On August 17, 2017 Defendant CLTD filed an application for patent protection for "Event Detection In An Implantable Auditory Prosthesis" for its cochlear implants. On February 4, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,549,094.

145. On September 7, 2017 Defendant CLTD filed an application for patent protection for "Implantable Medical Device with Multi-Band Loop Antenna" for its cochlear implants. On May 19, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,658,745.

146. On September 8, 2017 Defendant CLTD filed an application for patent protection for

"Controlling a Link For Different Load Conditions" for its cochlear implants. On May 12, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,652,667.

147. On September 15, 2017 Defendant CLTD filed an application for patent protection for "Hearing Implant Accessory" for its cochlear implants. On August 13, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number D856,522.

148. On October 24, 2017, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Signal Amplifier" for its cochlear implants. On October 22, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,455,334.

149. On November 17, 2017 Defendant CLTD filed an application for patent protection for "Cassette With Magnet" for its cochlear implants. On May 28, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number D849,740.

150. On November 20, 2017 Defendant CLTD filed an application for patent protection for "External Unit Of An Implanted Medical Device" for its cochlear implants. On February 11, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,556,110.

151. On November 20, 2017 Defendant CLTD filed an application for patent protection for "Stimulation Prosthesis With Configurable Data Link" for its cochlear implants. On June 9, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number RE48,039.

152. On December 21, 2017 Defendant CLTD filed an application for patent protection for "Implanted Auditory Prosthesis Control By Component Movement" for its cochlear implants. On May 26, 2020, the United States Patent and Trademark Office granted the request and issued

CLTD Patent Number 10,661,084.

153. On January 16, 2018 Defendant CLTD filed an application for patent protection for "Power Management Features" for its cochlear implants. On February 4, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,555,093.

154. On January 19, 2018 Defendant CLTD filed an application for patent protection for "Hearing Implant Accessory" for its cochlear implants. On October 1, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number D861,719.

155. On February 23, 2018, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Distributed Processing Of Electrophysiological Signals" for its cochlear implants. On April 9, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,252,054.

156. On February 23, 2018, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Outcome Tracking In Sensory Prostheses" for its cochlear implants. On April 23, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,271,147.

157. On February 26, 2018, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Implantable auditory prosthesis having isolated components" for its cochlear implants. On September 3, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,398,891.

158. On April 9, 2018 Defendant CLTD filed an application for patent protection for "Shifting Of Output In A Sense Prosthesis" for its cochlear implants. On April 7, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,610,687.

159. On April 20, 2018, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Stimulation Management" for its cochlear

implants. On October 1, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,426,957.

160. On May 1, 2018, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "System And Method For Improving Data Integrity And Power Efficiency" for its cochlear implants. On August 27, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,397,715.

161. On May 9, 2018, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Magnetic User Interface Controls" for its cochlear implants. On May 28, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,306,383.

162. On May 14, 2018 Defendant CLTD filed an application for patent protection for "Percutaneous Vibration Conductor" for its cochlear implants. On June 9, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,681,478.

163. On August 30, 2018, Defendant CLTD filed with the United States Patent and Trademark Office an application for patent protection for "Low-Power Active Bone Conduction Devices" for its bone-anchored hearing devices. On November 17, 2019, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,477,331.

164. On September 12, 2018 Defendant CLTD filed an application for patent protection for "Magnet Positioning In An External Device" for its cochlear implants. On March 3, 2020, the United States Patent and Trademark Office granted the request and issued CLTD Patent Number 10,582,318.

165. At all times relevant, CLTD directed CAM with respect to obtaining FDA regulatory approval to sell numerous CLTD-manufactured Class III medical devices in the United States,

including the Subject Cochlear Implant sold and delivered to Plaintiff in New York.

166. At all times relevant, CAM has acted at the specific direction and exclusive control of its parent corporation, CLTD, with respect to obtaining FDA regulatory approval to sell numerous CLTD-manufactured Class III medical devices in the United States, including the Cochlear Implant sold and delivered to Plaintiff in New York.

167. At all times relevant, CLTD advertised, marketed, and sold its Cochlear Nucleus CI512 medical devices, including Plaintiff's Subject Cochlear Implant, to medical providers and consumers in New York, including to Plaintiffs surgeon, hospital and Plaintiff.

168. In its Annual Report of 2017, CLTD represents that it has "a deep geographical reach, selling in over 100 countries, with a direct presence in over 20 countries and a global workforce of over 2,000 employees."

169. In its Annual Report of 2017, CLTD represents that it purposefully and intentionally directs its products into the United States and that "[s]urgeries for seniors, in the US in particular, are increasingly being driven by the Company's direct-to-consumer marketing campaigns."

170. At all times relevant, CLTD targeted medical providers and consumers in New York for the sale of Cochlear Nucleus CI512 medical devices, including Plaintiff's Subject Cochlear Implant.

171. At all times relevant, CLTD has advertised on its principal website, www.cochlear.com, the "Cochlear Awareness Network Events" that Defendants regularly sponsor and host in multiple locations in New York, where consumers like Plaintiff can "Explore how the Cochlear® Awareness Network can be a resource for those seeking information on advanced hearing loss solutions and provide support to those who have Nucleus® Cochlear Implant and Baha® technology!"

172. Through Cochlear's website www.cochlearcommunity.com, CLTD sponsors various meetings throughout the United States which it describes as being "for CI Users and family

members of CI users."

173. At all times relevant Defendants, both individually and collectively, were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, obtaining regulatory approval for, and introducing into the stream of commerce throughout the United States, including the forum state of New York, numerous products manufactured by CLTD, including Plaintiff's Subject Cochlear Implant.

174. As a result of all of the foregoing, Defendants sold and delivered the Subject Cochlear Implant in the forum state of New York.

175. As a result of all of the foregoing, Defendants' sale and delivery of the Subject Cochlear Implant in the forum state of New York was not simply an isolated occurrence, but rather arose from Defendants' efforts to create and serve the market for their products, including the Subject Cochlear Implant, in the forum state of New York.

176. As a result of all of the foregoing, the Subject Cochlear Implant was surgically implanted into the minor Plaintiff in Albany, Albany County, New York.

177. CLTD has regularly, and purposefully availed itself to the benefits and protections of the law of the United States by filing at least six (6) lawsuits in Federal Courts across the United States from 1990 through as recently as 2018.

178. In its Annual Report of 2014, CLTD states that its Hybrid System "was launched in the United States of America in April after the FDA granted regulatory approval" again establishing that CLTD intentionally, and purposefully avails itself to the consumer market and laws of the United States.

JURISDICTION AND VENUE

179. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because there is complete diversity of citizenship between Plaintiff and Defendants, and the

amount in controversy, exclusive of interest and costs, exceeds $75,000.

180. Venue is proper in this district pursuant to 28 U.S.C. §1391(b)(2), because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this district, including Plaintiff's receipt, surgical implantation and surgical removal of the Subject Cochlear Implant in Albany, Albany County, New York.

181. Defendants are subject to personal jurisdiction in this district because Plaintiff's claims arise from Defendants' actions in transacting business in the State of New York, and Defendants' commission of a tortious act in the State of New York.

182. Defendant CLTD's actions, by which it both purposefully availed itself to the forum state of New York and delivered Class III medical devices, including the Subject Cochlear Implant, into a stream of commerce that CLTD itself created with the knowledge and expectation that the medical devices it manufactured would be purchased by and surgically implanted into consumers in New York, such as the minor Plaintiff, include:

a. Establishing CAM as its wholly owned U.S. subsidiary to perform sales, marketing, distribution, service, finance, regulatory and administration of CLTD's products, including the Cochlear Implant, in the United States, including the forum state of New York, for the exclusive benefit of Cochlear.

b. Carrying on purposeful business activity in New York through its wholly owned subsidiary, CAM, which only markets and sells CLTD manufactured products, by such actions as having Plaintiff's hospital and Plaintiff as customers for its Class III medical devices, including the Subject Cochlear Implant;

c. Having actual knowledge and purposefully directing that the products that it manufactured, including the Subject Cochlear Implant, were being marketed and sold in the forum state of New York;

d. Targeting the forum state of New York by soliciting business in New York through its wholly owned subsidiary, CAM, as well as through its own CLTD website reasonably designed to reach consumers such as Plaintiff and Plaintiff's parents;

e. Purposefully availing itself to the laws and protections of the United States by marketing its products, including the Subject Cochlear Implant, to consumers, including Plaintiff and the minor Plaintiff's parents, by using CLTD's trademarks registered with the U.S. Patent and Trademark Office;

f. Purposefully availing itself to the laws and protections of the United States by protecting its intellectual property rights in its products marketed and sold in the United States, including New York, through the more than 200 patents issued to CLTD by the U.S. Patent and Trademark Office;

g. Performing testing services in New York on Cochlear manufactured Class III medical devices, including the Subject Cochlear Implant, through employees or agents of Defendants;

h. Filing lawsuits in multiple Federal Courts in the United States to protect its patents and trademarks; and

i. Identifying in its Annual Reports Cochlear Americas as a "Controlled Entity" of CLTD's for which CLTD has 100% ownership interest.

183. Defendants are subject to personal jurisdiction in this district in accordance with New York's long-arm statute and federal constitutional requirements because they have both purposefully availed themselves of the laws and protections of the forum state of New York, and Plaintiff's claims complained of herein arise out of and/or relate to both Defendants' transaction of business within the State of New York, and Defendants' commission of tortious acts within the State of New York which were the direct cause of Plaintiff's injuries complained of herein.

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FACTUAL BACKGROUND

Cochlear Implants

184. Cochlear Implants are surgically implanted medical devices that provide a sense of sound to people who are either profoundly deaf or severely hard of hearing.

185. The Cochlear Implant is intended to convert sound into electrical energy that activates the auditory nerve, which then sends the information to the brain, where it is interpreted as sound.

186. Plaintiff's Subject Cochlear Implant is part of a system that contains both internal and external components.

187. Plaintiff's Subject Cochlear Implant's system's external components include a sound processor and magnetic coil that are worn behind the ear.

188. Plaintiff's Subject Cochlear Implant's system's internal (surgically implanted) components include a receiver/stimulator that is housed in what is designed as, and is required to be a hermetically sealed (i.e. moisture impervious) titanium chassis; a platinum receiver coil; and an intra-cochlear electrode array. The internal components are surgically implanted into the mastoid portion of the skull, and into the cochlea (inner ear).

189. Plaintiff's Cochlear Implant's internal receiver/stimulator contains a feedthrough assembly that provides the connection between the electrical circuitry contained in the Cochlear Implant's intended-to-be hermetically sealed (i.e. moisture impervious) titanium chassis, and the Cochlear Implant's intra-cochlear electrode array.

190. The FDA approved a certain design, materials, construction, manufacturing method, testing, and labeling of Defendants' Cochlear Nucleus CI512 cochlear implant medical device pursuant to that agency's premarket approval process ("PMA").

191. The CI512 model cochlear implant was approved as supplement S048 to PMA P970051, which PMA was originally approved by the FDA on or about June 25, 1998. The FDA

approved PMA supplement S048 for the CI512 model cochlear implant on August 28, 2009.

192. Once a device has received PMA, the Medical Device Amendments of 1976 ("MDA"), 21 U. S. C. §360c et seq., forbid the manufacturer from making, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.

193. Once the FDA approves a medical device, any information that reasonably suggests that the device (1) "[m]ay have caused or contributed to a death or serious injury" or (2) "[h]as malfunctioned" and that any recurring malfunction that "would be likely to cause or contribute to a death or serious injury" must be reported to the FDA. 21 C.F.R. § 803.50(a); see 21 U.S.C. § 360i(a).

194. As is more fully set forth herein, with respect to Plaintiff's Subject Cochlear Implant, Defendants failed to comply with the specifications and requirements of the PMA, federal law and federal regulations. As a proximate result thereof, Plaintiff suffered injuries and damages of a personal and pecuniary nature.

THE COCHLEAR NUCLEUS CI500 RANGE FAILURE AND RECALL

195. Starting no later than November 2010, Defendants CLTD and CAM began receiving reports of malfunctions in the Cochlear Nucleus CI500 range of cochlear implant medical devices which occurred without any apparent external cause.

196. Starting no later than November 2010, Defendants CLTD and CAM began receiving explanted devices from the Cochlear Nucleus CI500 range which had malfunctioned. Defendants began performing failure analysis tests on those devices to determine the cause of the malfunctions.

197. Devices in the CI500 range, including the CI512 model, continued to malfunction without any apparent external cause through the end of 2010 and into the beginning of 2011.

198. Starting in March 2011, the number of complaints Defendants CLTD and CAM received monthly regarding devices malfunctioning without any apparent external cause more than doubled. Defendants CLTD and CAM continued to receive these explanted devices and continued to perform failure analysis tests.

199. Notwithstanding the alarming number of failures of the devices in the CI500 range, Defendants continued to market defective devices and continued to do so until complaints from CI implantation surgeons forced CAM to issue a nationwide recall.

200. Prior to Plaintiff's right-sided cochlear implant surgery on May 24, 2011, Defendants CLTD and CAM had received approximately one hundred (100) reports of malfunctioning CI500 implants, which included the Cochlear Nucleus CI512 model (the model of Plaintiff's Subject Cochlear Implant).

201. Upon information and belief, as a result of their failure analysis tests performed in late 2010 and early 2011, Defendants CLTD and CAM knew the CI500 range of implants had a problem with moisture leaking into the devices months before Plaintiff received his cochlear implant.

202. On or about September 13, 2011, the Australian government issued an urgent medical device recall and hazard alert in connection with unimplanted Cochlear Nucleus CI500 range of cochlear implant medical devices, which included the Cochlear Nucleus CI512 model (the model of Plaintiff's Subject Cochlear Implant).

203. The stated reason for the Australian governmental recall was that it followed a recent increase in the number of failures of Cochlear Nucleus CI512 model cochlear implants. The recall was considered a safety related recall.

204. In September 2011 Defendant CAM sent an "URGENT MEDICAL DEVICE RECALL" letter to its affected customers. The letter described the product, the problem, and

actions to be taken by the customers. The letter instructed customers to examine their inventory and quarantine the affected product.

205. On or about October 3, 2011 the FDA issued a Class 2 Recall, pursuant to Recall Number Z-0003-2012, for unimplanted Cochlear Nucleus CI512 model cochlear implants.

206. According to the FDA' s October 3, 2011 recall, the reason for the recall was that the recalled devices may shut down and cease to function.

207. According to the FDA, there was worldwide distribution of the recalled devices, including nationwide distribution in the United States.

208. On or about December 16, 2011, Defendant CLTD publicly released a letter from its CEO and president, Dr. Chris Roberts, stating the following:

> "This letter updates progress on investigations associated with the voluntary recall of unimplanted Nucleus CI500 series implants, specifically information on the root cause of the loss of hermeticity. The results of our investigation to date point to a loss of hermeticity from unexpected variations in the brazing process during manufacturing. Brazing is the process that joins the feedthrough to the titanium chassis. Variations in the brazing process have resulted in a limited number of implants being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps. These microcracks allow water molecules to enter the implant resulting in the malfunction of specific electronic components (typically one of four diodes).
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> The overall proportion of CI500 series devices that has failed is approximately 1.9% of registered implants globally with similar percentages in all three regions (The Americas, Europe Middle East & Africa (EMEA) and Asia Pacific). There were fewer reported failures in November 2011 than in October 2011."

209. On or about February 6, 2012 Defendant CLTD publicly released another letter from its CEO and president, Dr. Chris Roberts, advising, among other things, that:

> "This letter provides the latest information regarding the voluntary recall of unimplanted Nucleus CI500 series implants, specifically information regarding the latest observations associated with the number of reported devices failing, the failure mechanism and the clinical symptoms associated with the failure mechanism. In December 2011, we reported the root cause for the loss of hermeticity to be unexpected variations in the brazing process that joins the feedthrough to the titanium chassis during manufacturing. These variations resulted in a limited number of implants being more susceptible to developing microcracks m the braze joint during subsequent manufacturing steps. These microcracks allow water molecules to enter the implant resulting in the malfunction of specific electronic components (typically one of four diodes). Failure of these electronic components results in the implant shutting down. This failure mechanism continues to be consistent with no other failure mechanism associated with the loss of hermeticity identified. As of January 31st, 2012, the overall proportion of Nucleus CI500 series devices that has been reported as failed is 2.4% of registered devices globally ... "

210. Plaintiff has, at all times relevant herein, suffered from profound hearing loss.

211. Plaintiff was medically evaluated for a cochlear implant medical device, and determined to be an excellent candidate to receive a cochlear implant medical device.

212. On or about May 24, 2011, a Cochlear Nucleus CI5l2 cochlear implant medical device

designed, manufactured, distributed, and placed in the stream of commerce by Defendants, was surgically implanted into Plaintiff's body (right ear) at the Albany Medical Center, in Albany, Albany County, New York.

213. Thereafter, the minor Plaintiff's Subject Cochlear Implant failed. The Subject Cochlear Implant was surgically removed from Plaintiff's body on or about October 1, 2019, at the Albany Medical Center, in Albany, Albany County, New York due to the failure of the Subject Cochlear Implant's electronic components as a result of the Subject Cochlear Implant's loss of hermeticity and an "out- of-specification electronic assembly," according to CLTD's Returned Device Analysis Report and generated by CLTD itself.

214. Ergo, Plaintiff's Subject Cochlear Implant failed due to an electronic failure caused by a loss of hermeticity (i.e. failure of the moisture impervious seal) of the titanium chassis of the Subject Cochlear Implant' s internal receiver/stimulator as well as an "out-of-specification electronic assembly."

215. This loss of hermeticity in Plaintiff's Subject Cochlear Implant's internal receiver/stimulator was the result of unintended variations in the brazing process that occurred during Defendants' manufacture of Plaintiff's Cochlear Implant.

216. Brazing is the process that joined the feedthrough of Plaintiff's Subject Cochlear Implant to its titanium chassis.

217. These unintended variations m the brazing process during the manufacture of Plaintiff's Subject Cochlear Implant resulted in Plaintiff's Cochlear Implant being more susceptible to developing microcracks in its braze joint during subsequent manufacturing processes.

218. Microcracks developed in the braze joint of Plaintiff's Cochlear Implant during the manufacturing process.

219. Defendants thereafter failed to detect the microcracks in the Subject Cochlear

Implant's braze joint during its manufacturing process and related testing.

220. The microcracks in Plaintiff's Cochlear Implant's braze joint existed at the time that Plaintiff's Cochlear Implant left the Defendants' possession.

221. Microcracks in the braze joint of Plaintiff's Subject Cochlear Implant allowed water molecules to enter Plaintiff's Cochlear Implant and cause the malfunction and eventual failure of the Subject Cochlear Implant's electronic components and constituted a manufacturing defect which was causal to the Subject Cochlear Implant's failure and the minor Plaintiff's damages.

222. Additionally, during the manufacturing process, Defendants failed to manufacture the electronic assembly of the Subject Cochlear Implant according to their design and manufacturing specifications as set forth in the PMAs.

223. Defendants additionally failed to detect the out-of-specification electronic assembly in the Subject Cochlear Implant during its manufacturing process and related testing.

224. The out-of-specification electronic assembly was unintended by Defendants.

225. The out-of-specification electronic assembly existed at the time the Subject Cochlear Implant left the Defendants' possession.

226. The out-of-specification electronic assembly constituted a manufacturing defect which was causal to the Subject Cochlear Implant's failure and the minor Plaintiff's damages.

FEDERAL REQUIREMENTS:

227. The Cochlear Implant is a Class III medical device regulated by the United States Food and Drug Administration ("FDA").

228. The FDA requires a device that has received premarket approval, such as the Cochlear Implant, to be made with no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

229. Specifically, 21 C.F.R.§ 814.80 provides that "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."

230. A medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

231. Medical device manufacturers such as Defendants are required to comply with FDA regulation of medical devices in order to prohibit the introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices.

232. In addition to the conditions to approval specified in the PMA approval order for the medical device, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practices, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. 21 U.S.C. § 360j(f).

233. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 et seq.

234. Pursuant to 21 CFR § 820. l (c), the failure to comply with the provisions in Part 820 renders a device adulterated under section 501 (h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

235. Pursuant to 21 CFR § 820.30(g), each manufacturer of a medical device, such as Defendants, shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. 21 CFR § 820.30(g) (Emphasis added).

236. On Plaintiff's information and belief, at all times relevant Defendants failed to perform the mandated design validation by testing production units of the Cochlear Nucleus CI512 under actual or simulated use conditions, in violation of 21 CFR § 820.30(g).

237. Prior to the date that Plaintiff was implanted with the Subject Cochlear Implant, Defendants had received information that reasonably suggested that the Cochlear Nucleus CI512 "[m]ay have caused or contributed to a serious injury" or "malfunctioned" and that any recurring malfunction would be likely to cause or contribute to a death or serious injury of other recipients but failed to report this information to the FDA pursuant to 21 C.F.R. § 803.50(a) and 21 U.S.C. § 360i(a).

FAILURE TO ACHIEVE A HERMETIC SEAL

238. Plaintiff's Cochlear Implant experienced an unintended loss of hermeticity.

239. This loss of hermeticity was the result of unintended variations in the brazing process during Defendants' manufacture of Plaintiff's Cochlear Implant, and such unintended variations in the brazing process were contrary to the requirements of the PMA, federal law, and federal regulations.

240. Brazing is the metal-joining manufacturing process that joined the feedthrough of Plaintiff's Cochlear Implant to the receiver/stimulator's titanium chassis.

241. Unintended variations in the brazing process during Defendants' manufacture of

Plaintiff's Cochlear Implant that were contrary to the requirements of the PMA, federal law, and federal regulations, resulted in Plaintiff's Cochlear Implant being more susceptible to developing microcracks in its braze joint during Defendants' subsequent manufacturing steps.

242. As a result of these unintended variations in the brazing process during Defendants' manufacture of Plaintiff's Cochlear Implant, microcracks developed in Plaintiff's Cochlear Implant's braze joint during its manufacturing process, which process was contrary to the requirements of the PMA, federal law, and federal regulations.

243. Defendants failed to detect these microcracks in the braze joint of Plaintiff's Cochlear Implant during the manufacturing process, or after the manufacturing process but before the Cochlear Implant left Defendants' control, contrary to the requirements of the PMA, federal law, and federal regulations.

244. These micro cracks in the braze joint of Plaintiff's Cochlear Implant existed at the time that Plaintiff's Cochlear Implant left the possession of Defendants for sale, contrary to the requirements of the PMA, federal law, and federal regulations.

245. As a result of the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant at the time that Plaintiff's Cochlear Implant left the possession of Defendants for sale, Plaintiff's Cochlear Implant was adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation was not in conformity with federal requirements. See 21 U.S.C. § 351.

246. As a result of the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant at the time that Plaintiff's Cochlear Implant left the possession of Defendants, Plaintiff's Cochlear Implant was misbranded because, among other things, it was dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C.

§ 352.

247. Plaintiff's Cochlear Implant was adulterated pursuant to 21 U.S.C. § 351 because Defendants failed, among other things, to establish and maintain CGMP for Plaintiff's Cochlear Implant in accordance with 21 CFR § 820 et seq., as set forth above, by failing to perform the mandated design validation by testing production units of the Cochlear Nucleus CI512 under actual or simulated use conditions, in violation of 21 CFR § 820.30(g). As a result of Defendants' failure to establish and maintain CGMP as set forth above, Plaintiff's Cochlear Implant was adulterated, defective, and failed, resulting in injuries to Plaintiff.

248. If Defendants had complied with the federal requirements regarding CGMP in the manufacture of Plaintiff's Cochlear Implant, then Plaintiff's Cochlear Implant would have undergone manufacturing related testing in accordance with the PMA that would have revealed the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant at the time that Plaintiff's Cochlear Implant left the possession of Defendants for sale, such that the defective Cochlear Implant would not have been implanted in Plaintiff's body.

249. Additionally, during the manufacture of Plaintiff's Cochlear Implant, Defendants' unintended variations in the brazing process, and the microcracks that existed in the braze joint of Plaintiff's Cochlear Implant as a result thereof, deviated from the conditions of approval specified in the PMA order for the Cochlear Implant, and violated the PMA, CGMP, federal law and federal regulations because Defendants:

a. Failed to comply with MIL-STD-883 Test Method 1014 in the manufacture of the Cochlear Implant, by performing the "bubble test" before the "fine leak" test;

b. Failed to comply with MIL-STD-883 Test Method 2009 and/or JEDEC Standard in the manufacture of the Cochlear Implant;

c. Failed to comply with MIL-STD-883 Test Method 1018, by failing to properly set

calibrations in the equipment necessary for the proper functioning of the equipment;

d. Failed to qualify the Cochlear Implant using a hydrostatic pressure test and a corrosion test known, respectively, as QTP1190 and QTRl 190;

e. Failed to perform the QTPl 190 or the QTRl 190 tests as required or in the alternative, performed these tests improperly on the Cochlear Implant;

f. Failed to comply with the specified hermetic seal test procedures during the Cochlear Implant's manufacture;

g. Failed to perform the required visual inspections of the Cochlear Implant, and therefore failed to visualize the microcracks that existed in the Cochlear Implant' s braze joint;

h. Failed to follow the criteria for rejecting the Cochlear Implant as a result of the presence of microcracks in the Cochlear Implant's braze joint;

i. Failed to utilize the equipment, including the correct microscopic equipment, specified in the PMA necessary to observe the presence of microcracks in the Cochlear Implant's braze joint;

j. Failed to use alloy material in the Cochlear Implant's braze joint that was in compliance with specifications;

k. Failed to follow the process set forth in the PMA for the detection of alloy material that was not in compliance with the specifications, prior to using the noncompliant alloy material in the Cochlear Implant' s manufacturing process;

l. Employed a laser, resistance welder, or oven in the Cochlear Implant's manufacturing process that failed to conform to specifications;

m. Failed to control the environmental conditions inside the oven employed in the

Cochlear Implant's manufacturing process by failing to utilize temperatures specified;

n. Failed to inspect and control the hermetic sealing equipment used in the manufacture of the Cochlear Implant, including environmental control systems such as the laser and/or the manufacturing oven, to verify that such equipment and systems functioned as required;

o. Failed to utilize the manufacturing oven under the atmospheric conditions specified for the manufacture of the Cochlear Implant;

p. Failed to employ procedures in the manufacture of the Cochlear Implant to prevent contamination of the braze joint, as specified;

q. Failed to maintain procedures in the manufacture of the Cochlear Implant for the identification and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the quality of the Cochlear Implant, as required;

r. Failed to establish and maintain procedures in the manufacturing process to control cochlear implants, including Plaintiffs Cochlear Implant, that failed to conform to specified requirements;

s. Failed to develop, conduct, control, and monitor its production processes as required to ensure that the Cochlear Implant conformed to specifications;

t. Misbranded the Cochlear Implant by concealing known risks, in violation of 21 C.F.R. §§803.50(a)(l) and 806.10(a)(l);

u. Failed to perform design validation testing including accelerated life cycle testing in an environment mimicking the human implant environment, in violation of 21

CFR 820.30(g);

v. Failed to validate the entire device, not just component parts, as required;

w. Failed to execute properly on the manufacturing floor by failing to execute pursuant to the FDA baseline set of documents in the PMA relating to manufacturing processes necessary to prevent microcracks in the Cochlear Implant's braze joint;

x. Violated specific CGMP in the manufacture of the Cochlear Implant, including the failure to conduct management reviews with sufficient frequency, failure to establish required auditing, training, operating, testing, and quality assurance procedures including supplier quality procedures and audits;

y. Failed to conduct adequate post-marketing surveillance of the Cochlear Nucleus CI512, as required;

z. Failed to notify and warn the public, including Plaintiff or Plaintiffs physician, of reported incidents of failure, necessitating surgery, personal injury attendant to the failure, thus misrepresenting the safety of the Cochlear Implant;

aa. Failed to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the Cochlear Nucleus CI512 at all times prior to Plaintiffs injuries having manifested themselves, as required;

bb. Continued to promote and market the Cochlear Nucleus CI512 despite their knowledge of these risks at the time that Plaintiff was implanted with the Subject Cochlear Implant;

cc. Failed to inspect environmental control systems, including those in the manufacturing oven, to verify that the systems functioned pursuant requirements; and

dd. Failed to report to the FDA information that Defendants received that reasonably

suggested that the Cochlear Nucleus CI512 cochlear implants (1) "[m]ay have caused or contributed to a serious injury" or "malfunctioned" and that any recurring malfunction would be likely to cause or contribute to a death or serious injury but failed to report this information pursuant to 21 C.F.R. § 803.50(a) and 21 U.S.C. § 360i(a).

OUT-OF-SPECIFICATION ELECTRONIC ASSEMBLY

250. Plaintiff's Cochlear Implant also failed because of an unintended out-of-specification electronic assembly.

251. This out-of-specification electronic assembly was the result of unintended deviations in the manufacturing process during Defendants' manufacture of Plaintiff's Subject Cochlear Implant, and such unintended deviations were contrary to the requirements of the PMA, federal law, and federal regulations.

252. The electronic assembly include the electrodes and electrode array that runs from inside the Subject Cochlear Implant's chassis through Plaintiff's cochlea.

253. Defendants failed to detect this unintended out-of-specification electronic assembly during the manufacturing process, or after the manufacturing process but before the Subject Cochlear Implant left Defendants' possession, contrary to the requirements of the PMA, federal law, and federal regulations.

254. This unintended out-of-specification electronic assembly in Plaintiff's Subject Cochlear Implant existed at the time that Plaintiff's Cochlear Implant left the possession of Defendants for sale, contrary to the requirements of the PMA, federal law, and federal regulations.

255. As a result of the unintended out-of-specification electronic assembly in Plaintiff's Subject Cochlear Implant that existed at the time that Plaintiff's Cochlear Implant left the possession of Defendants for sale, Plaintiff's Cochlear Implant was adulterated pursuant to 21 U.S.C. § 351

because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation was not in conformity with federal requirements. See 21 U.S.C. § 351.

256. As a result of the unintended out-of-specification electronic assembly in Plaintiff's Subject Cochlear Implant that existed at the time that Plaintiff's Cochlear Implant left the possession of Defendants, Plaintiff's Subject Cochlear Implant was misbranded because, among other things, it was dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

257. Plaintiff's Subject Cochlear Implant was adulterated pursuant to 21 U.S.C. § 351 because Defendants failed, among other things, to establish and maintain CGMP for Plaintiff's Subject Cochlear Implant in accordance with 21 CFR § 820 et seq., as set forth above, by failing to perform the mandated design validation by testing production units of the Cochlear Nucleus CI512 under actual or simulated use conditions, in violation of 21 CFR § 820.30(g). As a result of Defendants' failure to establish and maintain CGMP as set forth above, Plaintiff's Cochlear Implant was adulterated, defective, and failed, resulting in injuries to Plaintiff.

258. If Defendants had complied with the federal requirements regarding CGMP in the manufacture of Plaintiff's Subject Cochlear Implant, then Plaintiff's Subject Cochlear Implant would have undergone manufacturing related testing in accordance with the PMA that would have revealed the unintended out-of-specification electronic assembly in Plaintiff's Subject Cochlear Implant at the time that Plaintiff's Subject Cochlear Implant left the possession of Defendants for sale, such that the defective Subject Cochlear Implant would not have been implanted in Plaintiff's body.

259. Additionally, during the manufacture of Plaintiff's Subject Cochlear Implant, Defendants' unintended deviations in said process resulting in the manufacture of an out-of-specification electronic assembly in Plaintiff's Subject Cochlear Implant, deviated from the conditions of approval

specified in the PMA order for the Cochlear Implant, and violated the PMA, CGMP, federal law and federal regulations because Defendants:

a. Failed to comply with the specified electronic assembly procedures during the Subject Cochlear Implant's manufacture;

b. Failed to perform the required visual inspections of the Subject Cochlear Implant, and therefore failed to visualize the out-of-specification electronic assembly that existed in the Subject Cochlear Implant;

c. Failed to follow the criteria for rejecting the Subject Cochlear Implant as a result of the presence of an out-of-specification electronic assembly in the Subject Cochlear Implant;

d. Failed to utilize the equipment, including the correct microscopic equipment, specified in the PMA necessary to observe the presence of an out-of-specification electronic assembly in the Subject Cochlear Implant;

e. Failed to use the electronic assembly in the Subject Cochlear Implant that was in compliance with specifications;

f. Failed to follow the process set forth in the PMA for the detection of an out-of-specification electronic assembly that was not in compliance with the specifications, prior to using the noncompliant electronic assembly in the Subject Cochlear Implant' s manufacturing process;

g. Employed a technique in the manufacturing process of the Subject Cochlear Implant's electronic assembly that failed to conform to specifications;

h. Failed to employ procedures in the manufacture of the Subject Cochlear Implant to prevent the manufacture of an out-of-specification electronic assembly;

i. Failed to maintain procedures in the manufacture of the Subject Cochlear Implant for the identification and removal of out-of-specification electronic assemblies which could reasonably be

expected to have an adverse effect on product quality to ensure that it is removed from the Subject Cochlear Implant and replaced with an electronic assembly that was within the design and manufacturing specifications the Subject Cochlear Implant, as required;

j. Failed to establish and maintain procedures in the manufacturing process to control cochlear implants, including Plaintiff's Subject Cochlear Implant, that failed to conform to specified requirements;

k. Failed to develop, conduct, control, and monitor its production processes as required to ensure that the Subject Cochlear Implant conformed to specifications;

l. Misbranded the Cochlear Implant by concealing known risks, in violation of 21 C.F.R. §§803.50(a)(l) and 806.10(a)(l);

m. Failed to perform design validation testing including accelerated life cycle testing in an environment mimicking the human implant environment, in violation of 21 CFR 820.30(g);

n. Failed to validate the entire device, not just component parts, as required;

o. Failed to execute properly on the manufacturing floor by failing to execute pursuant to the FDA baseline set of documents in the PMA relating to manufacturing processes necessary to prevent an out-of-specification electronic assembly in Plaintiff's Subject Cochlear Implant;

p. Violated specific CGMP in the manufacture of the Subject Cochlear Implant, including the failure to conduct management reviews with sufficient frequency, failure to establish required auditing, training, operating, testing, and quality assurance procedures including supplier quality procedures and audits;

q. Failed to conduct adequate post-marketing surveillance of the Cochlear Nucleus CI512, as required;

r. Failed to notify and warn the public, including Plaintiff, Plaintiff's parents or Plaintiff's physician, of reported incidents of failure, necessitating surgery, personal injury attendant to the failure, thus misrepresenting the safety of the Subject Cochlear Implant;

s. Failed to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the Cochlear Nucleus CI512 at all times prior to Plaintiff's injuries having manifested themselves, as required;

t. Continued to promote and market the Cochlear Nucleus CI512 despite their knowledge of these risks prior to and at the time that Plaintiff was implanted with the Subject Cochlear Implant;

u. Failed to report to the FDA information that Defendants received that reasonably suggested that the Cochlear Nucleus CI512 cochlear implants (1) "[m]ay have caused or contributed to a serious injury" or "malfunctioned" and that any recurring malfunction would be likely to cause or contribute to a death or serious injury but failed to report this information pursuant to 21 C.F.R. § 803.50(a) and 21 U.S.C. § 360i(a).

260. As a result of Defendants' deviations from the conditions of approval specified in the PMA order for the Subject Cochlear Implant, as well as CGMP, federal law and federal regulations, as set forth above, Plaintiff's Subject Cochlear Implant was adulterated, defective, and failed, which was both causal to the failure and Plaintiff's injuries.

FIRST CAUSE OF ACTION:

STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT

261. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

262. Defendants designed, manufactured, distributed, sold, supplied and placed in the stream of commerce Plaintiff's Subject Cochlear Implant.

263. Plaintiff's Subject Cochlear Implant that Defendants designed, manufactured, distributed, sold, supplied, and placed in the stream of commerce was defective in its manufacture, construction, or composition when it left the hands of Defendants in that Plaintiff's Subject Cochlear Implant deviated in a material way from the PMA, CGMP, Defendants' approved product specifications, Defendants' approved manufacturing performance standards, and/or other applicable federal law and federal regulations applicable to Plaintiff's Subject Cochlear Implant, as described above, posing a serious risk of medical device failure and associated medical treatment, including surgical procedures to remove the Cochlear Implant and replace it with a non-defective cochlear implant medical device. This conduct rendered the Subject Cochlear Implant defective, adulterated, and more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

264. Plaintiff's Subject Cochlear Implant that Defendants designed, manufactured, distributed, sold, supplied and placed in the stream of commerce was expected to and did reach Plaintiff without a substantial change in the condition in which it was sold.

265. As a direct and proximate result of Plaintiff's use of the Subject Cochlear Implant Designed, manufactured, distributed, sold, supplied and placed in the stream of commerce by Defendants, and Defendants' failure to comply with the PMA, CGMP, Defendants' approved product specifications, Defendants' approved manufacturing performance standards, and other applicable federal law and federal regulations applicable to Plaintiff's Subject Cochlear Implant, Plaintiff suffered serious physical injury, harm, damages, economic loss and will continue to suffer such harm, damages, and economic loss in the future.

266. Defendants' acts and omissions as alleged in this Complaint constitute conscious disregard for human safety, warranting the imposition of punitive damages.

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SECOND CAUSE OF ACTION:

STRICT PRODUCTS LIABILITY FAILURE TO WARN

267. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

268. Defendants violated a state-law duty of care by failing to report known risks associated with the use of the Subject Cochlear Implant to the FDA.

269. Defendants failed to adequately warn health care professionals and the public, including Plaintiff, Plaintiff's parents and Plaintiffs physician, of the true risks of Plaintiffs Subject Cochlear Implant, including the propensity to fail, causing pain and suffering and requiring further treatment, including surgery. Defendants failed to comply with their duty under federal law and breached their duty to use reasonable care under applicable state negligence law.

270. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Plaintiff's Subject Cochlear Implant.

271. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

272. As a direct and proximate result of the conduct of Defendants, as described above, Plaintiff suffered or will suffer serious and permanent noneconomic and economic injuries.

273. Defendants' conduct, as described above, was reckless. Defendants risked the lives and health of consumers, including Plaintiff, based on the suppression of knowledge relating to the safety and efficacy problems with Plaintiff's Subject Cochlear Nucleus model CI512. Defendants made a conscious decision not to notify the FDA as required by law, thereby putting increased profits over the public safety, including Plaintiff's safety. Defendants' actions and omissions as alleged in this Complaint demonstrate a conscious disregard for human safety,

warranting the imposition of punitive damages.

THIRD CAUSE OF ACTION:

NEGLIGENCE

274. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

275. Defendants had a duty to exercise ordinary care in following the PMA, CGMP, federal law and federal regulations in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of Plaintiff's Subject Cochlear Implant into the stream of commerce.

276. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of Plaintiff's Subject Cochlear Implant into the stream of commerce in that Defendants knew or should have known that Plaintiff's Subject Cochlear Implant had a propensity to fail and cause bodily harm and was not safe for use by consumers due to Defendants' failure to comply with the PMA, CGMP, federal law or federal regulations, as described above.

277. Defendants had a duty to exercise ordinary care in the advertising and sale of Plaintiff's Subject Cochlear Implant, including a duty to warn Plaintiff, Plaintiff's parents or Plaintiff's physician of the dangers associated with the Cochlear Implant that were known or should have been known to Defendants at the time of sale to Plaintiff.

278. Defendants failed to exercise ordinary care in the advertising and sale of Plaintiff's Subject Cochlear Implant by failing to warn Plaintiff, Plaintiff's parents or Plaintiff's physician of the dangers associated with the Cochlear Implant that were known or should have been known to Defendants at the time of sale to Plaintiff. Defendants failed to warn Plaintiff, Plaintiff's parents or Plaintiff's physician that the Subject Cochlear Implant had a propensity to fail, cause

bodily harm and require surgical replacement due to Defendants' failure to follow the PMA, CGMP, federal law and federal regulations, as described above.

279. Defendants had a duty to exercise ordinary care in the labeling of the Subject Cochlear Implant and failed to issue adequate pre-marketing or post-marketing warnings to physicians, Plaintiff or the general public, regarding the propensity of the Subject Cochlear Implant to fail, cause bodily harm and require surgical replacement all due to Defendants' failure to follow the PMA, CGMP, federal law and federal regulations, as described above.

280. Despite the fact that Defendants knew or should have known that the Subject Cochlear Implant posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Cochlear Nucleus CI512 for use by consumers, including Plaintiff, even though they failed to comply with the PMA, CGMP, federal law and federal regulations with respect to this medical device, as described above.

281. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

282. Defendants' conduct breached their duty of ordinary care to Plaintiff by failing to exercise ordinary care under the circumstances.

283. As a direct and proximate result of Defendants' acts and omissions, Plaintiff suffered serious physical injury, harm, damages and economic loss, including but not limited to undergoing surgery, pain and suffering and will continue to suffer such harm, damages and economic loss in the future.

284. Defendants conduct as described herein was reckless. Defendants risked the life and health of Plaintiff through the sale of the Subject Cochlear Implant with knowledge of the safety and efficacy problems and suppressed this knowledge from the FDA and the general public,

including Plaintiff. Upon information and belief, Defendants made conscious decisions not to notify the FDA, or warn or inform the unsuspecting consuming public, including Plaintiff. Defendant placed profits before public safety. Defendants' actions and omissions as alleged in this Complaint demonstrate a conscious disregard for human safety, warranting the imposition of punitive damages.

FOURTH CAUSE OF ACTION:

NEGLIGENCE PER SE

285. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

286. Defendants had a duty to exercise ordinary care in following the PMA, CGMP, federal law and federal regulations in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of Plaintiff's Subject Cochlear Implant into the stream of commerce.

287. Defendants failed to exercise ordinary care in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of Plaintiff's Subject Cochlear Implant into the stream of commerce in that Defendants knew or should have known that Plaintiff's Subject Cochlear Implant had a propensity to fail and cause bodily harm and was not safe for use by consumers, including Plaintiff, because Defendants failed to comply with the PMA, CGMP, federal law or federal regulations, as described above.

288. Despite the fact that Defendants knew or should have known that the Subject Cochlear Implant posed a serious risk of bodily harm to consumers, including Plaintiff, Defendants continued to manufacture and market the Cochlear Nucleus CI512 for use by consumers, including Plaintiff, even though they failed to comply with the PMA, CGMP, federal law and federal regulations with respect to this medical device, as described above.

289. Plaintiff, as the recipient of the Subject Cochlear Implant, is within the class of persons the statutes and regulations described above are designed to protect and Plaintiff's injuries complained of herein are the type of harm these statutes and regulations are designed to prevent.

290. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

291. Defendants' conduct breached their duty of ordinary care to Plaintiff by failing to exercise ordinary care under the circumstances.

292. As a direct and proximate result of Defendants' acts and omissions, Plaintiff suffered serious physical injury, harm, damages and economic loss, including but not limited to undergoing surgery, pain and suffering and will continue to suffer such harm, damages and economic loss in the future.

293. Defendants' conduct as described herein was reckless. Defendants risked the life and health of Plaintiff through the sale of the Subject Cochlear Implant with knowledge of the safety and efficacy problems and suppressed this knowledge from the FDA and the general public, including Plaintiff. Upon information and belief, Defendants made conscious decisions not to notify the FDA, or warn or inform the unsuspecting consuming public, including Plaintiff. Defendant placed profits before public safety. Defendants' actions and omissions as alleged in this Complaint demonstrate a conscious disregard for human safety, warranting the imposition of punitive damages.

WHEREFORE, Plaintiffs pray for judgment and relief against the Defendants, and each of them, as follows:

1. For general damages in an amount within the jurisdictional limits of this court;

2. Past, future medical and related items of expense, according to proof;

3. For loss of future earnings and earning capacity, according to proof;

4. For prejudgment interest;

5. For punitive damages;

6. For costs of suit and attorney fees, if awarded by the court, incurred herein; and

7. For such other and further relief as to the Court appears just and proper.

Dated: July 3, 2020

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